Supplementary list of materials

This list is intended to provide supplementary guidance to the HTA's broader policy framework on 'relevant material'.

The list is not intended as exhaustive or exclusive, but is intended to provide guidance to stakeholders in respect of a number of materials that guidance on the status of, as relevant material or otherwise, has previously been sought. The HTA will review and update the list periodically.

The list currently refers solely to which human body parts, tissues and cells are defined as 'relevant materials' for the purposes of the Human Tissue Act 2004, in line with the statutory definition above. The HTA intends to expand the list in the future to also provide guidance to the human application sector on which 'tissues and cells' are regulated under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

Where a material is not included within the following list stakeholders should refer to the policy framework to formulate their own assessment of the material's status in line with the guidance provided in the framework.

Materials classified in the following list as relevant material are done so subject to the following general caveat that they are relevant material except where:

- They have divided or been created outside the human body
- They have been treated, processed or lysed through a process intended to render them acellular. This would include the freezing or thawing of cells only where that process is intended to render the material acellular.

Material	**Relevant Materials for the purposes of the Human Tissue Act 2004?**
Antibodies	No
Artificially created stem cells*	No
Bile	Yes
Blood	Yes
Bone marrow	Yes
Bones/skeletons	Yes
Brain	Yes
Breast Milk***	Yes
Breath condensates and exhaled gases	No

Buffy coat layer (interface layer between plasma and blood cells when blood is separated)	Yes
Cell lines**	No
Cells that have divided in culture	No
CSF (Cerebrospinal fluid)	Yes
Cystic fluid	Yes
DNA	No
Eggs*	No
Embryonic stem cells (cells derived from an embryo)**	No
Embryos (outside the body)*	No
Extracted material from cells, e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids.	No
Faeces	Yes
Fetal tissue	Yes
Fluid from cystic lesions	Yes
Gametes*	No
Hair (from deceased person)	Yes
Hair (from living person)	No
Joint aspirates	Yes
Lysed cells	No
Mucus	Yes
Nail (from deceased person)	Yes
Nail (from living person)	No
Nasal and bronchial lavage	Yes
Non blood derived stem cells (i.e. derived from the body.)	Yes
Non fetal products of conception (i.e. the amniotic fluid, umbilical cord, placenta and membranes)	Yes
Organs	Yes
Pericardial fluid	Yes
Plasma (Please note: Depending on how plasma is prepared and processed, it may contain small numbers of platelets and other blood cells. If any of these cells are present then the plasma must be regarded as relevant material.)	No
Platelets	Yes
Pleural fluid	Yes
Primary cell cultures (whole explant/biopsy present)	Yes
Pus	Yes
RNA	No

Saliva	Yes
Serum	No
Skin	Yes
Sperm*	No
Sputum (or phlegm)	Yes
Stomach contents	Yes
Teeth	Yes
Tumour tissue samples	Yes
Umbilical cord blood stem cells	Yes
Urine	Yes

* While outside the definition of relevant material for the purposes of the HT Act, these materials fall under the remit of the Human Fertilisation and Embryology Act 1990, and are regulated by the Human Fertilisation and Embryology Authority (HFEA).

** Cell lines and embryonic stem cell lines fall within the regulatory remit of the HTA by virtue of the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which regulates the processing, storage and distribution of stem cell lines for human application. Both the HFEA and the Medicines and Healthcare products Regulatory Agency (MHRA) also have a regulatory remit in respect of cell lines and embryonic stem cell lines. A joint position statement issued by the HTA, HFEA and MHRA provides guidance on the relevant regulatory remits.

*** Breast milk does not constitute tissue or cells for human application under the (Quality and Safety for Human Application) Regulations 2007, but is classified as relevant material for the purposes of the Human Tissue Act 2004 where stored or used for a scheduled purposes.